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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Haim Emil Dahan

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EXAMINER

SHELL, LAURA C

ART UNIT

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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/774,939	Applicant(s) DAHAN ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8,12-15,19,20,23 and 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,9-11,16-18,21,22,24-26 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/2/09, 2/1/10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

Claim 1 and consequently all dependent claims, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As claim 1 is currently worded, the claimed invention does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter). The examiner recognizes that Applicant wishes to claim a process, however, there are no process steps being claimed, instead only "providing" steps are claimed. "Providing" is an abstraction which does not result in a transformation (change from one physical state to another) and there is no machine implementation (the method is not being performed by a machine). "Providing" is simply to "make available" or a "condition" and with this reasonable interpretation neither a transformation or machine implementation occurs.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolridge et al. ("The continuous measurement of milk intake at a feed in breast-fed

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babies"). Woolridge discloses a method of measuring fluid flow from a fluid source to a baby's mouth through a nipple (Fig. 1 on page 366) comprising: providing a feeding pathway for fluid flow from the fluid source to the baby's mouth, wherein the feeding pathway has a first opening in communication with the fluid source and a second opening in communication with the baby's mouth (please see the marked up version of Fig. 1 at the end of the office action. As seen and labeled in the marked up version of Fig. 1 at the end of the office action, the nipple has multiple openings through the wall/thickness of the nipple. Fig. 1 discloses via the cross-section of the nipple that the thickness of the wall of the nipple creates individual pathways between the entrance opening and the exit opening, wherein the entrance opening is equivalent to the first opening in communication with the fluid source and the exit opening is equivalent to the second opening in communication with the baby's mouth. As disclosed in Fig. 1, there is a pathway between the two openings. Therefore the examiner is interpreting any one of the pathways as being the feeding pathway. Please note that Applicant has not claimed any structure to distinguish the feeding pathway from the pathways disclosed in Woolridge.); and providing an indicator pathway separate from the feeding pathway for indicating the amount of fluid provided to the baby's mouth through the feeding pathway, wherein the indicator pathway has a first opening in communication with the fluid source and a second opening in direct fluid communication with the baby's mouth (the examiner is interpreting the indicator pathway to be any one of the other pathways besides the feeding pathway, as shown in Fig. 1. As noted above, Fig. 1 discloses that the nipple has a pathway between the entrance and exit openings (which are equivalent

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to the first and second openings). Please note that Applicant has not claimed any structure in claim 1 that would differentiate the indicator pathway from the feeding pathway. It is the examiner's position that since all the milk flowing through the flow transducer will end up flowing through each of the five pathways, the amount of milk flowing through each pathway is equivalent to the total amount of milk flowing through the flow transducer divided by five. Therefore the amount of milk flowing through one pathway is equivalent to the amount of milk flowing through any of the other pathways. Line 8 of the third paragraph on page 367 discloses that the nipple shield has five pathways/holes. Again, please note that Applicant has not claimed any structure to differentiate the claimed pathways from the pathways disclosed in Woolridge) and wherein the indicator pathway includes at least one intermediate chamber among segments of the indicator pathway (it is the examiner's position that any portion of the pathway can be interpreted as the intermediate chamber as Applicant has not claimed any structure regarding the intermediate chamber, nor any structure regarding segments of a pathway. For instance, possible segments in the pathway disclosed by Woolridge can include a first segment adjacent the first opening, a middle segment in the middle of the pathway, and a third segment adjacent the second opening), whereby the amount of fluid drawn into the indicator pathway and the at least one intermediate chamber is indicative of the amount of fluid drawn into the feeding pathway (It is the examiner's position that since all the milk flowing through the flow transducer will end up flowing through each of the five pathways, the amount of milk flowing through each pathway is equivalent to the total amount of milk flowing through the flow transducer

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divided by five. Therefore the amount of milk flowing through one pathway is equivalent to the amount of milk flowing through any of the other pathways).

In reference to claim 6, Woolridge discloses that the feeding pathway and the indicator pathway are integral to the nipple (Fig. 1).

In reference to claim 9, Woolridge discloses that the fluid comprises breast milk and wherein the feeding pathway and the indicator pathway are adapted to receive the breast milk from a mother's breast (Fig. 1).

Claims 16, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolridge et al. ("The continuous measurement of milk intake at a feed in breast-fed babies"). Woolridge discloses an apparatus (Fig. 1 on page 366) comprising: a feeding pathway for fluid flow from the fluid source to the baby's mouth, wherein the feeding pathway has a first opening in communication with the fluid source and a second opening in communication with the baby's mouth (please see the marked up version of Fig. 1 at the end of the office action. As seen and labeled in the marked up version of Fig. 1 at the end of the office action, the nipple has multiple openings through the wall/thickness of the nipple. Fig. 1 discloses via the cross-section of the nipple that the thickness of the wall of the nipple creates individual pathways between the entrance opening and the exit opening, wherein the entrance opening is equivalent to the first opening in communication with the fluid source and the exit opening is equivalent to the

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second opening in communication with the baby's mouth. As disclosed in Fig. 1, there is a pathway between the two openings. Therefore the examiner is interpreting any one of the pathways as being the feeding pathway. Please note that Applicant has not claimed any structure to distinguish the feeding pathway from the pathways disclosed in Woolridge.); and an indicator pathway separate from the feeding pathway for indicating the amount of fluid provided to the baby's mouth through the feeding pathway, wherein the indicator pathway has a first opening in communication with the fluid source and a second opening in direct fluid communication with the baby's mouth (the examiner is interpreting the indicator pathway to be any one of the other pathways besides the feeding pathway, as shown in Fig. 1. As noted above, Fig. 1 discloses that the nipple has a pathway between the entrance and exit openings (which are equivalent to the first and second openings). Please note that Applicant has not claimed any structure in claim 1 that would differentiate the indicator pathway from the feeding pathway. It is the examiner's position that since all the milk flowing through the flow transducer will end up flowing through each of the five pathways, the amount of milk flowing through each pathway is equivalent to the total amount of milk flowing through the flow transducer divided by five. Therefore the amount of milk flowing through one pathway is equivalent to the amount of milk flowing through any of the other pathways. Line 8 of the third paragraph on page 367 discloses that the nipple shield has five pathways/holes. Again, please note that Applicant has not claimed any structure to differentiate the claimed pathways from the pathways disclosed in Woolridge) and wherein the indicator pathway includes at least one intermediate chamber among segments of the indicator pathway (it

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is the examiner's position that any portion of the pathway can be interpreted as the intermediate chamber as Applicant has not claimed any structure regarding the intermediate chamber, nor any structure regarding segments of a pathway. For instance, possible segments in the pathway disclosed by Woolridge can include a first segment adjacent the first opening, a middle segment in the middle of the pathway, and a third segment adjacent the second opening), whereby the amount of fluid drawn into the indicator pathway and the at least one intermediate chamber is indicative of the amount of fluid drawn into the feeding pathway (It is the examiner's position that since all the milk flowing through the flow transducer will end up flowing through each of the five pathways, the amount of milk flowing through each pathway is equivalent to the total amount of milk flowing through the flow transducer divided by five. Therefore the amount of milk flowing through one pathway is equivalent to the amount of milk flowing through any of the other pathways).

In reference to claim 21, Woolridge discloses that the feeding pathway and the indicator pathway are integral to the nipple (Fig. 1).

In reference to claim 24, Woolridge discloses that the fluid comprises breast milk and wherein the feeding pathway and the indicator pathway are adapted to receive the breast milk from a mother's breast (Fig. 1).

Claims 31, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolridge et al. ("The continuous measurement of milk intake at a feed in breast-fed babies"). Woolridge discloses a method of indicating suction from a baby's suckling comprising: receiving suction from a baby's mouth (when a baby's sucks on the nipple suction is received and pulls the milk toward the baby's mouth); providing the suction to at least a first pathway and a second pathway separate from the first pathway (please see the marked up version of Fig. 1 at the end of the office action. As seen and labeled in the marked up version of Fig. 1 at the end of the office action, the nipple has multiple openings through the wall/thickness of the nipple. Fig. 1 discloses via the cross-section of the nipple that the thickness of the wall of the nipple creates individual pathways between the entrance opening and the exit opening, wherein the entrance opening is equivalent to the first opening in communication with the fluid source and the exit opening is equivalent to the second opening in communication with the baby's mouth. As disclosed in Fig. 1, there is a pathway between the two openings and lines 7-8 of the third paragraph on page 367 discloses that there are five openings/pathways); the suction drawing fluid from a fluid source into the first pathway and the second pathway, wherein the first and second pathways are in direct fluid communication with the baby's mouth (Fig. 1); and indicating in the second pathway the presence of the suction (Applicant has not claimed any details on how the 'indicating' is performed, therefore the examiner is interpreting the flow of milk through the second pathway to the baby as the presence of suction).

In reference to claim 33, Woolridge discloses that indicating in the second pathway the presence of suction comprises indicating the presence of suction by the amount of fluid drawn into the second pathway (the flow transducer measure the flow drawn into the area where the pathways start, if the flow through the transducer drops from previous levels it can be interpreted as an indication that there is suction lacking through one or more of the pathways).

In reference to claim 36, Woolridge discloses that the amount of fluid drawn into the second pathway is indicative of an amount of fluid drawn into the first pathway (It is the examiner's position that since all the milk flowing through the flow transducer will end up flowing through each of the five pathways, the amount of milk flowing through each pathway is equivalent to the total amount of milk flowing through the flow transducer divided by five. Therefore the amount of milk flowing through one pathway is equivalent to the amount of milk flowing through any of the other pathways).

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Larsson (US Patent No. 4,687,466). Larsson discloses an apparatus comprising: a feeding pathway for fluid flow from a fluid source to a baby's mouth, wherein the feeding pathway has a first opening in communication with the fluid source and a second opening in communication with the baby's mouth (Fig. 1 discloses the device and one of tubes 15 can be interpreted as the feeding pathway with the first opening in communication with the fluid source disclosed in Fig. 2, and the second opening in communication with the

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baby's mouth disclosed in Fig. 1 as the distal end of the tube near 16); and an indicator pathway separate from the feeding pathway for indicating the amount of fluid provided to the baby's mouth through the feeding pathway, wherein the indicator pathway has a first opening in communication with the fluid source and a second opening in direct fluid communication with the baby's mouth (Fig. 1 discloses the device and one of tubes 15 can be interpreted as the indicator pathway with the first opening in communication with the fluid source disclosed in Fig. 2, and the second opening in communication with the baby's mouth disclosed in Fig. 1 as the distal end of the tube near 16) and wherein the indicator pathway includes at least one intermediate chamber among segments of the indicator pathway (it is the examiner's position that any portion of the pathway can be interpreted as the intermediate chamber as Applicant has not claimed any structure regarding the intermediate chamber, nor any structure regarding segments of a pathway), Whereby the amount of fluid drawn into the indicator pathway and the at least one intermediate chamber is indicative of the amount of fluid drawn into the feeding pathway (since both pathways are equal in size and length and share the same fluid source, the fluid drawn into one pathway is indicative of the fluid drawn into the other pathway. Please note that Applicant has not claimed that the fluid must be drawn through both pathways simultaneously).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolridge et al. ("The continuous measurement of milk intake at a feed in breast-fed babies"). Woolridge discloses the device substantially as claimed including that the indicator and feeding pathways each have a length and a cross-sectional area, however, Woolridge does not disclose that the cross-sectional area of the indicator pathway is substantially smaller than the cross-sectional area of the feeding pathway, nor that the length of the indicator pathway is substantially longer than the length of the feeding pathway. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Woolridge's device such that the cross-sectional area of indicator pathway is smaller and the length of the indicator pathway is longer than that of the feeding pathway as these would have involved changes in size and a change in size is generally recognized as being within the level of ordinary skill in the art.

Claims 7, 22, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolridge et al. ("The continuous measurement of milk intake at a feed in breast-fed babies") in view of Paige (US 2004/0055987). Woolridge discloses the device substantially as claimed including an indicator pathway and an intermediate chamber, however, Woolridge does not disclose that there are gradations along the indicator pathway and intermediate chamber. Paige, however, discloses a similar device (Figs. 1 and 4) in which a nipple is used to deliver fluid to a baby and gradations are present along the fluid pathway (the length of the nipple is the fluid/indicator pathway).

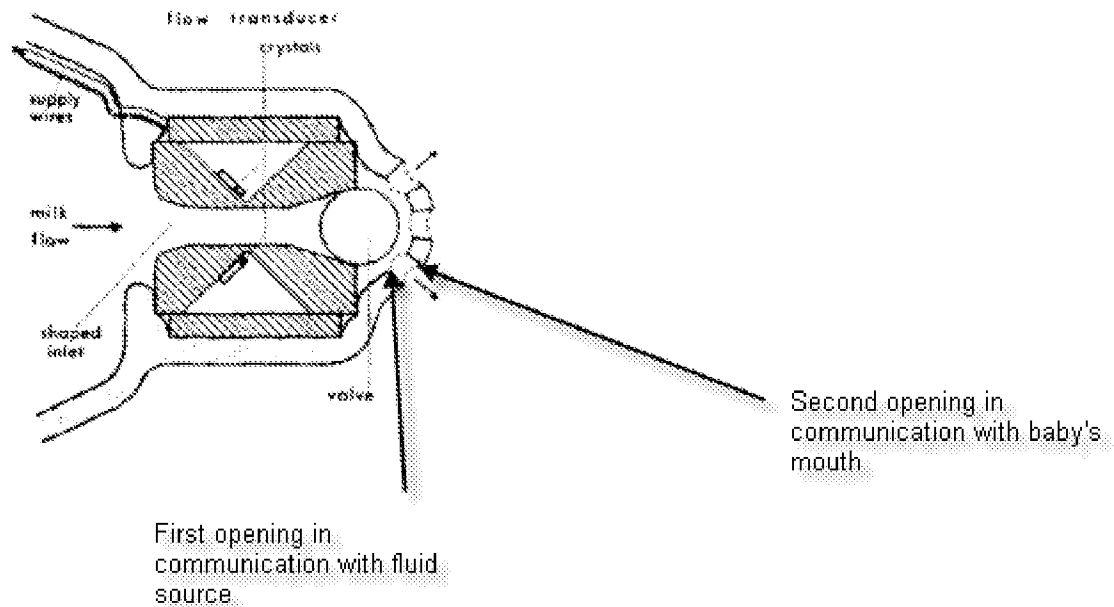
Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Woolridge's device by placing gradations along the indicator pathway and intermediate chamber as taught by Paige, in order to provide a fluid delivery device with visual confirmation to the user/mother of how much fluid is being ingested by the baby which allows the user/mother to track fluid ingested to make sure the baby is eating healthfully.

Claims 10, 11, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolridge et al. ("The continuous measurement of milk intake at a feed in breast-fed babies") in view of Buckley et al. (US Patent No. 6,109,100). Woolridge discloses the device substantially as claimed except for the fluid source being a bottle and the indicator pathway including a check-valve to prevent backflow of fluid. Buckley, however, discloses a similar fluid delivery device (Figs. 1-5) in which the fluid source is a bottle (21 for example) and the fluid indicator pathway includes a check-valve (Fig. 3,

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35 for example). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Woolridge's device by placing the flow meter in the nipple of a bottle and by including a check-valve, as taught by Buckley, in order to diversify the device and allow the same fluid-metering/tracking concept to be used by mother's who bottle-feed their baby's as well as to prevent fluid from flowing backwards and comprising the accuracy of the measurement of fluid flow.

Claim 35 is rejected under 35 U.S.C. 103(a) as being obvious over Woolridge et al. ("The continuous measurement of milk intake at a feed in breast-fed babies") in view of Bommarito et al. (US Patent No. 6,741,523). Woolridge discloses the device substantially as claimed except for a color code in the fluid pathway to indicate presence of fluid. Bommarito, however, discloses color codes for fluid pathways to indicate the presence of fluid in the pathways (col. 27, lines 32-35). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Woolridge with the color-coded fluid presence indicator, as taught by Bommarito, in order to provide a device with multiple indicators that are easily read and understood by the average individual.



Response to Arguments

Applicant's arguments, see pages 2-6, filed 11/2/2009, with respect to the rejection(s) of claim(s) 1-3, 6, 7, 9-11, 16-18, 21, 22, 24-26, 31-36 under Kron have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Woolridge and Larsson.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is

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(571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767